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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,791	03/25/2004	Christian Viskov	03806.0599-01000	6028

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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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06/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/808,791

Applicant(s)

VISKOV ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-33 and 35-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-33 and 35-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 24-33 and 35-49 are presented for reconsideration on the merits.

Response to Amendment

The amendment filed March 30, 2007, has been received and entered. The extension of time is duly noted. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Foreign Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on September 23, 2002. It is noted that Applicants have filed a certified copy of the France 02 11724 application as required by 35 U.S.C. 119(b).

Claims 24-33 and 35-49 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-16 of copending Application No. 10/808,410 in view of US Patent No. 5744132 and US Patent No. 6617316. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two sets of copending claims is scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims of instant case are drawn to method for analyzing heparins by depolymerizing heparin in a sample with heparinases, optionally reducing the sample, and assaying the sample by HPLC (High Performance Liquid Chromatography).

Copending claims are drawn to method of assaying a sample by depolymerizing a sample with heparinases, and assaying the sample using reverse chromatography.

US Pat No. '132 teaches reverse phase chromatography, see figure 11.

US Pat.No. '316 teaches depolymerizing with heparinases and SAX chromatography, see column 2, lines 33-48 and column 3, line 27.

The claims differ as noted above in terms of their scope of how the claims are drafted, however, the same steps are effectively employed except reverse phase is used and not HPLC.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to employ the steps of the copending claims in a method of depolymerizing heparin in a sample as claimed herein. Expected successful results would have been obtained by selecting the functional equivalent of reverse phase chromatography as disclosed by US Pat No. '132 and one of skill would have been motivated to select heparinases for depolymerization based upon the teachings of the copending claims and what is known in the art as taught by US Pat Nos. '316 and '132. The claims are prima facie obvious because each of the copending claims teaches the claimed features as set forth in the instant case.

Response to Arguments

Applicant's arguments filed March 30, 2007 have been fully considered but they are not persuasive. However, Applicants' request is duly noted.

Claims 24-33 and 35-49 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-18 of copending Application No. 10/808,409. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two sets of copending claims is scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims of instant case are drawn to method for analyzing heparins by depolymerizing heparin in a sample with heparinases, optionally reducing the sample, and assaying the sample by Chromoatography for the content of the sample.

Copending claims are drawn to methods of quantifying a sample by by depolymerizing a sample with heparinases, and assaying the sample by Chromoatography to determine glycoserine.

The claims differ as noted above in terms of their scope of how the claims are drafted, however, the same steps are effectively employed except there are particulars with respect to the chromatography employed and glycoserine is being analyzed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to employ the steps of the copending claims in a method of depolymerizing heparin in a sample to determine content as claimed herein. Expected successful results would have been obtained for analyzing the same sample for any desired component (i.e. glycoserine) using the similar method steps differing only in the scope of how the two sets of claims are claimed. One of skill would have been motivated to select heparinases for depolymerization and/or a treating step based upon the teachings of the copending claims. The claims are prima facie obvious because each of the copending claims teaches the claimed features as set forth in the instant case.

Response to Arguments

Applicant's arguments filed March 30, 2007 have been fully considered but they are not persuasive. However, Applicants' request is duly noted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-33 and 35-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mourier et al (US Patent No. 6617316), discussed above in view of Debie (US Patent No. 5,389,618) both cited on enclosed PTO-1449 Form, Lopez (US Patent No. 4,981,955), Sasisekharan et al (US Patent No. 5,569,600), Petitou et al (US Patent No. 4,801,583) and Bergendal et al (US Patent No. 5,039,529), all of these cited on enclosed PTO-892 Form.

Claims are discussed above. Further, the oligosaccharides present are modified with a 1,6-anhydro bond.

Mourier et al teach method for analyzing heparins comprising depolymerizing a sample with heparinases, and assaying by HPLC, see column 2, lines 30-35 and line 48 and column 3, line 13 and lines 27-28. Further, the oligosaccharides present are modified with a 1,6-anhydro bond and the chromatography is anion exchange, see column 1, line line 27 and column 8, lines 1-15. Also, Mourier et al teach method for

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analyzing heparins comprising depolymerizing a sample with a mixture of heparinases, and assaying by HPLC, see column 2, lines 30-35 and line 48 and column 3, line 13 and lines 27-28.

Debrie teaches enoxaparin and mobile phase chromatography region up to 206nm wherein phosphate salt buffer is used. Note column 6, lines 66-67 and column 7, line 1 and 30.

Lopez teaches reducing agent for depolymerized heparin, i.e. sodium borohydride (alkali metal salt of borohydride), note column 5, line 45.

Sasisekharan et al teach mixture of heparinases, including I, II and III, note column 4, lines 30-37.

Petitou et al teach also oligosaccharide comprising at least one 1,6-anhydro residue, note column 16, lines 3 and 26.

Bergendal et al teach acetylated sugars and detection of components, see column 2, lines 35-37 and see figure 1.

The claims differ from the teachings of Mourier et al in that a mixture of enzymes, reducing agent: borohydride, enoxaparin, mobile phase and acetylated sugars are not specifically disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Mourier et al, Debie, Lopez, Sasisekharan et al, Petitou et al and Bergendal et al in order to provide for an analyzing method for enoxaparin selecting a mixture of heparinases of I, II, III, for which to depolymerize and then reduce the depolymerizant with borohydride for detection of components such as acetylated sugars as all of these claimed features are disclosed by the secondary cited references. One of skill would have expected successful results for depolymerizing enoxaparin and to then reduce it by the disclosed agent is clearly taught.

Further, to detect other components, such as acetylated sugars, upon applying mobile phase and HPLC chromatography for analyzing a sample containing heparin is clearly within the skill of an artisan. Further, to modify the oligosaccharides with 1,6-anhydro bond is clearly an obvious modification as it is clearly prevalent and disclosed by Petitou et al to be an obvious and desirable bond for which to modify oligosaccharide components from a depolymerized sample as disclosed by Mourier et al. One of skill would have been motivated to perform the steps as claimed because they are clearly disclosed in the cited prior art for analyzing a heparin containing sample. Furthermore, depolymerization with a mixture of heparinases is clearly disclosed as well. In the

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absence of unexpected successful results the claims are rendered prima facie obvious over the cited prior art.

Response to Arguments

Applicant's arguments filed March 30, 2007, have been fully considered but they are not persuasive. The argument that the method is not disclosed by Mourier et al is noted. However, Mourier et al in combination with the cited prior art do disclose a method for analyzing heparins comprising depolymerizing a sample with a mixture of heparinases, and assaying by HPLC, see column 2 of Mourier et al, at lines 30-35 and line 48 and column 3, line 13 and lines 27-28.

The prior art combination at least suggests exhaustively depolymerizing a sample or one of ordinary skill in the art would have been motivated to modify as necessary a depolymerizing step well known in the art to completely depolymerize if one of skill should so choose to do so. Debie teaches enoxaparin and mobile phase chromatography region up to 206nm wherein phosphate salt buffer is used.

Note column 6, lines 66-67 and column 7, line 1 and 30, while clearly meets the range as claimed. Also, Bergendal et al teach strong binding of copper ions is shown by the high affinity of these fractions for a copper Chelex column, e.g. not being eluted by a water solution, a high salt solution, corresponding to a 0.5M to 2M or 3M solution of NaCl, or a high salt solution of a neutral or almost neutral buffer solution; thus, there is at least some suggestion to exclude NaCl.

Furthermore, all of the other cited references do not use NaCl and do not even mention it in their disclosures. Therefore, there is satisfactory suggestion in the cited

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prior art combination to exclude NaCl as claimed herein. The claims remain prima facie obvious for these reasons and those of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Deborah K. Ware
June 23, 2007



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 128 1657